

NELAP Accrediting Authorities' (AA) Policy and Implementation of Section 2.5 of the
NELAC 2003 Standard
Performance Testing (PT) Samples must be Analyzed as Routine Samples.
(Approved by AA s 1-22-04 and 3-03-04)

Section 2.5 of the NELAC standard states the following:

“The samples shall be analyzed and the results returned to the PT Provider no later than 45 calendar days from the scheduled study shipment date. The laboratory’s management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples”.

NELAP Accrediting Authorities (AA) shall assess the laboratory’s compliance with the requirements of this section of the standards during data review and on-site assessments. The laboratories shall be penalized for violations in accordance with the NELAC standards and the AA’s due process rules.

The AAs at a minimum will check for the following:

1. Pt Samples are entered into the laboratory sample receipt log as samples and are tracked through the laboratory as routine environmental samples.
2. PT samples received as ampules are diluted according to the PT provider’s instructions. The diluted ampule becomes the routine environmental sample. The sample is added to a routine sample batch.
3. PT samples are digested and extracted as routine environmental samples.
4. Instructions shall be included in the laboratory’s standard operating procedure (SOP) for how low level samples will be analyzed, including concentration of the sample or adjustment of the normality of a titrant. When a PT sample falls below the range of their routine analytical method the low-level SOP may be used.
5. PT samples that consist of a set of individual samples, e.g. microbiology PTs, shall be analyzed according to the laboratory’s routine procedures.
6. PT samples shall not be analyzed multiple times unless routine environmental samples are analyzed multiple times. Results from multiple analyses must be calculated in the same manner as routine environmental samples.
7. The type, composition, concentration, and frequency of quality control samples analyzed with the PT samples shall be the same as with routine environmental samples.

8. Initial and continuing calibrations shall be at the same frequency as with routine environmental samples.
9. The AA must make a documented determination when exceptions to any of these requirements are applicable on the basis of the laboratory's routine environmental sample composition and their SOPs.

AAs that find a PT Provider directing or suggesting that laboratories use additional QC, offering QC samples that are specifically designed for a given PT, or providing instructions beyond sample preservation and preparation of ampules, shall report the actions to the NELAC PT Board with documentation.